

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0137]

DDM

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Control	A. Corbin

Levothyroxine Sodium Therapeutic Equivalence; Public Meeting; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until September 23, 2005, the comment period for the May 23, 2005, public meeting on the therapeutic equivalence of levothyroxine sodium drug products that was announced in the **Federal Register** of April 20, 2005 (70 FR 20574). The public meeting included FDA staff and representatives of three medical societies: The American Thyroid Association (ATA), the Endocrine Society, and the American Association of Clinical Endocrinologists (AACE). FDA is taking this action in response to a request for an extension.

DATES: Submit written or electronic comments on or before September 23, 2005.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Rose Cunningham, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600

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SUPPLEMENTARY INFORMATION:

I. Background

On May 23, 2005, FDA cosponsored a public meeting on the therapeutic equivalence of levothyroxine sodium drug products. The meeting included FDA staff and representatives of three medical societies: The ATA, the Endocrine Society, and the AACE. The purpose of the meeting was to discuss FDA's regulatory standards and methodological approaches for determining therapeutic equivalence between levothyroxine sodium drug products. FDA asked interested constituencies, including patient advocacy and education groups, and pharmaceutical sponsors, to submit comments by July 23, 2005.

By letter dated July 6, 2005, Abbott Laboratories (Abbott) requested that FDA extend the date for submission of comments. Abbott requested the extension to give interested parties the opportunity to comment meaningfully on the matters discussed at the meeting. The transcript became available on July 12, 2005.

FDA has decided to reopen the comment period until September 23, 2005.

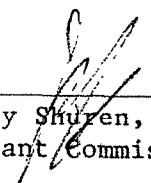
II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics discussed at the May 23, 2005, meeting. Submit two copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Transcript

The transcript of the May 23, 2005, meeting is available on FDA's Web site at <http://www.fda.gov/cder/meeting/levothyroxine2005.htm>.

Dated: 8/16/05
August 10, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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